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John V. Hanley Reg. No. 38,171

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of

Inventor: Octavian Iancea, et al.

Serial No. 10/090,472

Filed: March 4, 2002

For: MODULAR GRAFT COMPONENT

JUNCTIONS

Examiner: Vy Q. Bui

Group Art Unit: 3731

Client ID: ENDOV-55672

Date: October 5, 2006

APPELLANT'S BRIEF

MS: Appeal Brief Patents Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This Appellant's Brief is being filed in response to the final Office action dated April 4, 2006. The required fees are submitted herewith. In the event additional fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper.

This brief contains items under the following headings, and in the order set forth below:

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- I. REAL PARTY IN INTEREST
- II. RELATED APPEALS AND INTERFERENCES
- III. STATUS OF CLAIMS
- IV. STATUS OF AMENDMENTS
- V. SUMMARY OF CLAIMED INVENTION
- VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
- VII. ARGUMENT
- VIII. CLAIMS APPENDIX
- IX. EVIDENCE APPENDIX
- X. RELATED PROCEEDINGS APPENDIX

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: EndoVascular Technologies, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a wholly-owned subsidiary of Boston Scientific Corporation, 1 Boston Scientific Place, Natick, MA 01760.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the applicant.

III. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The claims in the application are: Claims 1, 2 and 4-17.

B. Status of All of the Claims

Each of pending claims 1, 2 and 4-17 stand as finally rejected under 35 U.S.C. § 102(b) or in the alternative, under 35 U.S.C. § 103(a).

C. Claims on Appeal

The claims on appeal are each of pending claims 1, 2 and 4-17.

IV. STATUS OF AMENDMENTS

The claims finally rejected on April 4, 2006 are the claims on appeal. No amendment has been filed or entered subsequent to the final rejection.

V. SUMMARY OF CLAIMED INVENTION

As recited in independent claim 1, the present invention is directed towards a modular graft device for treating vasculature (See page 5, line 2 et seq. of the specification; FIGS. 1-4; and original claim 1). The modular graft device includes a first graft component 30 including a first wall and a second graft component 80 including a second wall (e.g. graft material 83).

Further, the second graft component 80 includes a frame (See FIGS. 1 and 2; distal stent 85) with a plurality of radially extending components (reference 86). Upon assembling the first 30 and second 80 graft components, the radial components 86 extend through both the first and second walls (See also page 14, line 10 et seq.).

Moreover, the second graft component 80 further includes a plurality of pre-fabricated holes 87, at least one pre-fabricated hole 87 being in alignment with one radially extending component 86 (See original claim 3; and page 15, line 1 et seq.).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 2, 4-11 and 13 were improperly rejected under 35 U.S.C. § 102(b) or in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Marcade (5,683,449).

VII. ARGUMENT

In the final Office action dated April 5, 2006, the Examiner rejected claims 1, 2, 4-11 and 13 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Marcade (5,683,449). In so rejecting the claims, the Examiner referred to Column 13, lines 53-57 of the Marcade patent as support for the teaching of using sutures or barbs to secure two graft-stent components together. The Examiner then stated "Inherently, the barbs will extend through holes in the graft to secure two stent-graft components together. Notice that the holes in the graft must be pre-fabricated before withdrawing the delivery catheter which deliver the stent-graft device to a location in a blood vessel." The Examiner further stated that "Alternatively, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide pre-fabricated holes in the graft or the barbs to extend through both stent-graft components to secure both the stent graft components together." The Examiner then separately rejected claims 3, 12 and 14-17 under § 103(a) as being unpatentable over Marcade.

It is respectfully submitted, however, that independent claim 1 and dependent claims 2 and 4-17 are allowable over the cited Marcade reference. Significantly, each of the pending claims recite a modular device including a plurality of pre-fabricated holes, at least one pre-fabricated hole being in alignment with one radially extending component. Notably, the rationale behind the pre-fabricated holes relates to preventing the radially extending components

from tearing the graft material of a graft component. The cited Marcade reference, however, neither contemplates nor specifically addresses such an approach but rather, teaches barbs or hooks which are forced through graft material. It is submitted that the concept of pre-fabricated holes at least one of which is in alignment with a radially extending component is clearly distinct from holes formed by forcing a barb or hook through graft material. Accordingly, it is respectfully submitted that the Marcade reference does not anticipate the subject matter recited in independent claim 1 and its dependent claims since it simply does not teach the concept of a prefabricated hole.

Furthermore, it is respectfully submitted that a *prima facia* case of obviousness has not been presented by the Examiner. Notably, MPEP 2143.01 provides that "The mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination" and that "A statement that modifications of the prior art to meet the claimed invention would have been '<u>well within the ordinary skill in the art</u> at the time the claimed invention was made' because the references relied upon teach all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facia* case of obviousness without some objective reason to combine the teachings of the references."

It is respectfully submitted that no evidence has been provided to support a conclusion that one of ordinary skill in the art would have incorporated pre-fabricated holes into the device disclosed by the Marcade reference. Moreover, it is respectfully submitted that the Examiner's statement that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide fabricated holes "to secure both the stent-graft components together" falls short of providing a rational basis supporting an obviousness conclusion. The Marcade reference

simply does not recognize any alternative to forcing barbs or hooks through graft material and

thus, one of ordinary skill in the art would not have been motivated, upon reading the Marcade

reference, to modify its teachings to include pre-fabricated holes.

Therefore, it is respectfully submitted that independent claim 1 as well as its dependent

claims 2 and 4-17 define subject matter which is allowable over the cited art.

CONCLUSION

For all the reasons stated above, Applicant respectfully submits that the Examiner has

erred in rejecting claims 1, 2 and 4-17. It is respectfully requested that the Board reverse the

rejection of the claims and pass claims 1, 2 and 4-17 to issue.

Respectfully submitted,

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VIII. CLAIMS

Claim 1 (previously presented): A modular endovascular graft device for treating vasculature, comprising:

a first graft component having a first wall; and

a second graft component having a second wall, the second graft component including a frame with a plurality of radially extending components which upon assembling the first and second components, at least one of the plurality of the radially extending components extends through both the first wall and the second wall, and further including a plurality of pre-fabricated holes, at least one pre-fabricated hole being in alignment with one radially extending component.

Claim 2 (previously presented): The device of claim 1, wherein the frame is in the form of a self-expanding stent.

Claim 4 (previously presented): The device of claim 1, wherein the plurality of radially extending components are in the form of hooks or barbs.

Claim 5 (previously presented): The device of claim 4, wherein the hooks or barbs have sharpened points.

Claim 6 (previously presented): The device of claim 4, wherein the hooks or barbs are pointed in a caudal direction.

Claim 7 (previously presented): The device of claim 1, wherein the radially extending component has a length sufficient to extend through the wall of the first graft component and into a wall of vasculature.

Claim 8 (previously presented): The device of claim 1, the first graft component further comprising a superior end and an inferior end, the inferior end including at least one limb support section.

Claim 9 (previously presented): The device of claim 1, wherein the first graft component is bifurcated.

Claim 10 (previously presented): The device of claim 1, wherein the second graft component has a tubular configuration.

Claim 11 (previously presented): The device of claim 1, wherein the second graft has a proximal end and distal end, the distal end including a self-expanding stent.

Claim 12 (previously presented): The device of claim 1, further comprising fuzzy tufts of yarn configured at a junction between the first and second components.

Claim 13 (previously presented): The device of claim 1, further comprising additional graft components, each having a wall and including a frame with a plurality of radially extending components which, upon assembling each additional component and the previously assembled components, at least one of the plurality of radially extending components extend through both the wall of the additional component and the wall of at least one of the previously assembled components such that a successive chain of assembled components is formed.

Claim 14 (previously presented): The device of claim 1, one or more components reinforced with a thin coating of a biocompatible elastomer applied to the graft material.

Claim 15 (previously presented): The device of claim 14, the biocompatible elastomer applied to specific areas of the graft material.

Claim 16 (previously presented): The device of claim 14, the biocompatible elastomer a polyurethane co-polymer dip-coated onto the surface of the graft material.

Claim 17 (previously presented): The device of claim 1, the graft material weave pattern of one or more components altered to provide extra strength.

IX. EVIDENCE APPENDIX
NONE

X. RELATED PROCEEDINGS APPENDIX NONE